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EXAMINER	
HE, AMY	

ART UNIT	PAPER NUMBER
2858	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,569	IDE, TORU	
	Examiner	Art Unit	
	Amy He	2858	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 6-18* is/are rejected.

7)☒ Claim(s) *4 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/17/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1, 6-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toru Ide et al. "An Artificial Lipid Bilayer Formed on An Agarose-Coated Glass for Simultaneous Electrical And Optical Measurement of Single Ion Channels" (Biochemical and Biophysical Research Communication Vol. 265, No. 2, p.595-599, 1999), in view of Vogel et al. (U. S. Patent No. 7, 201,836).

As for claims 1 and 10, Toru Ide et al. discloses (in Figures 2A) a current measuring device, which is capable of measuring a current flowing via an artificial lipid bilayer membrane(see page 596, left column, under the section heading "The bilayer membrane chamber"), comprising:

an upper solution chamber (the upper chamber as shown in Figure 2A) which is capable of containing aqueous solution; and

a lower solution chamber (lower chamber) disposed below the upper solution chamber, a bottom of the upper solution chamber having a membrane formation opening (the hole/pore on the bottom of the upper chamber), a bottom of the lower solution chamber having a support layer (coverslip) for supporting the artificial lipid bilayer membrane, the artificial lipid bilayer membrane formed on the membrane

formation opening (the hole/pore) of the upper solution chamber being brought into contact with the support layer(coverslip) so as to be supported,

said current measuring device further comprising the artificial lipid bilayer membrane formed on the membrane formation opening (the hole/pore) is swollen to a side of the lower solution chamber so as to be made thinner and come into contact with the support layer (coverslip) so that the artificial lipid bilayer membrane is supported on the support layer(i.e. the artificial lipid bilayer membrane is swollen to the side of the lower solution chamber so as to be made thinner naturally after a period of time, or by controlling the hydrostatic pressure of the chambers; and the membrane comes into contact with the coverslip and is supported on the coverslip, see the section under the heading "Bilayers on the Agarose-Coated Glass Formation" on page 597); and

optical observation means (the total internal reflection fluorescence microscope, or TIRFM, see the abstract on page 595) which allows observation of the artificial lipid bilayer membrane on the support layer.

Still referring to claims 1 and 10, Toru Ide et al. does not specifically disclose a bottom plate made of translucent material, on which the support layer is placed; and an interval keeping member for keeping a predetermined interval between the upper solution chamber and the bottom plate, so that the lower solution chamber is provided by being surrounded with the bottom plate and the interval keeping member.

Vogel et al. discloses (see Figure 7; col. 24, lines 20-40) using a bottom plate made of translucent material (carrier plate 206 made of glass) and an interval keeping member (spacer 212) for keeping a predetermined interval between an upper solution

chamber (194a) and the bottom plate (206), so that a lower solution chamber (194b) is provided by being surrounded with the bottom plate (206) and the interval keeping member (212), for the purpose of providing a support for the substrate and associated system components, and increasing the system reliability (see col. 24, lines 20-40).

A person of ordinary skill in the art would find it obvious at the time the invention was made to modify Toru Ide et al. to incorporate the use of a bottom plate made of glass and an interval keeping member for keeping a predetermined interval between the upper solution chamber and the bottom plate, as taught by Vogel et al., so that the coverslip is supported on the bottom plate, and the lower solution chamber is provided by being surrounded with the bottom plate and the interval keeping member, for the purpose of providing a support for the components of the current measuring device, and increasing the reliability of the current measuring device (see col. 24, lines 20-40).

As for claims 6-7, Toru Ide et al. disclose that the support layer (coverslip in Figure 2A) is made of polymer gel, or agarose (see page 596, left column, the section under the heading "Formation of a bilayer on agarose-coated glass", lines 5-6).

As for claims 8 and 14, Toru Ide et al. discloses that the thickness of the support layer (coverslip in Figure 2A) made of the polymer gel is 50 nm or more and 2 mm or less (0.17 mm, see page 596, left column, the section under the heading "Formation of a bilayer on agarose-coated glass", line 5).

As for claim 9, Toru Ide et al. discloses that the diameter of the membrane formation opening is 10um or more and 500um or less (30um, page 596, right column, Figure 1B).

As for claim 11, Toru Ide et al. discloses a current measuring means electrically connected to the upper solution chamber; and earthing means electrically connected to the lower solution chamber (see Figure 2A; also see the section "The Bilayer membrane chamber" on page 596).

As for claim 12, Toru Ide et al. discloses that the artificial lipid bilayer membrane includes an ion channel (see page 598, left column, Figure 3).

2. Claims 2-3, 13 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toru Ide et al. "An Artificial Lipid Bilayer Formed on An Agarose-Coated Glass for Simultaneous Electrical And Optical Measurement of Single Ion Channels" (Biochemical and Biophysical Research Communication Vol. 265, No. 2, p.595-599, 1999) in view of Vogel et al. (U. S. Patent No. 7, 201,836), and further in view of Rubinsky et al. (U. S. Patent No. 6, 300,108).

As for claims 2 and 3, Toru Ide et al. in view of Vogel et al. discloses the current measuring device as set forth in claim 1.

Toru Ide et al. in view of Vogel et al. does not specifically disclose a negative pressure generation means for dropping an internal pressure of the lower solution chamber provided by being surrounded with the bottom plate and the interval keeping member, wherein the negative pressure generation means causes the artificial lipid bilayer membrane formed on the membrane formation opening of the upper solution chamber to swell to the side of the lower solution chamber; and that the negative pressure generation means is formed in the interval keeping member and includes (i) a

suction port which allows connection between the lower solution chamber and an outside and (ii) sucking means which is connected to the suction port so as to suck the aqueous solution in the lower solution chamber.

Rubinsky et al. discloses a negative pressure generation means (the syringe and the outlet channels for drawing liquid from the lower chamber in Figure 1) for dropping an internal pressure of the lower solution chamber (col.6, lines 62-64; col. 7, lines 58-64); wherein the negative pressure generation means includes (i) a suction port (the outlet channel in Figure 1) which allows connection between the lower solution chamber and an outside and (ii) sucking means (the syringe) which is connected to the suction port so as to suck the aqueous solution in the lower solution chamber(col.6, lines 62-64; col. 7, lines 58-64).

A person of ordinary skill in the art would find it obvious at the time the invention was made to further modify Toru Ide et al. in view of Vogel et al. to dispose in the interval keeping member or at any other convenient places, a negative pressure generation means that includes a suction port and a sucking means, as taught by Rubinsky et al., for the purpose of controlling the movement of the biological cells in the lipid bilayer membrane by controlling the internal pressure of the lower solution chamber and causing the artificial lipid bilayer membrane formed on the membrane formation opening of the upper solution chamber to swell to the side of the lower solution chamber much faster and in a controlled manner as compared to the natural process(col. 7, lines 53-64).

As for claim 13, Toru Ide et al. disclose that the support layer (coverslip in Figure 2A) is made of polymer gel (agarose, see page 596, left column, the section under the heading "Formation of a bilayer on agarose-coated glass", lines 5-6).

As for claim 15, Toru Ide et al. discloses that the diameter of the membrane formation opening is 10um or more and 500um or less (30um, page 596, right column, Figure 1B).

As for claim 16, Toru Ide et al. in view of Vogel discloses a bottom plate made of a translucent material (Vogel et al. reference, carrier plate 206 made of glass; Figure 7), and an optical observation means (the total internal reflection fluorescence microscope, or TIRFM of Toru Ide et al. reference, see the abstract on page 595; or the optical analyzing system of Vogel, col. 25, lines 27-45), which allows observation of the artificial lipid bilayer membrane on the support layer is provided below the bottom plate.

As for claim 17, Toru Ide et al. discloses a current measuring means electrically connected to the upper solution chamber; and earthing means electrically connected to the lower solution chamber (see Figure 2A; also see the section "The Bilayer membrane chamber" on page 596).

As for claim 18, Toru Ide et al. discloses that the artificial lipid bilayer membrane includes an ion channel (see page 598, left column, Figure 3).

Allowable Subject Matter

3. Claims 4-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. The following is a statement of reasons for the indication of allowable subject matter:

Claims 4-5 are allowable because none of the prior art discloses a current measuring device comprising an interval keeping member capable of changing an interval between an upper chamber and a bottom plate, the change of the interval causes an artificial lipid bilayer membrane to swell to the side of the lower solution chamber, and in the combination as claimed.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy He whose telephone number is (571) 272-2230. The examiner can normally be reached on 8:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Hirshfeld can be reached on 571-272-2168. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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